Lambda Research Newsletter

February 2019

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Research Accelerated

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Clinical Research NEWSletter

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GLOBAL NEWS

1. Global influenza pandemic ranks third on WHO threat list 2019

According to the World Health Organization (WHO), influenza pandemic ranks third in the threat list of 2019. WHO has initiated a five year plan to tackle these threats, starting this year.

The 5-year plan is also known as the 13th general programme of work, which plans to achieve these targets based on the devised Sustainable Development Goals (SDG).

Influenza pandemic is a major threat for the world. The affected country needs to have strong surveillance and needs to use appropriate strategies to fight against this disease. WHO is part of the Global Influenza Surveillance and Response System (GISRS). WHO recommends certain flu vaccines to protect against seasonal flu every year.

WHO partners, stakeholders and policy makers ensure that appropriate diagnostic tools, vaccines and antivirals are available. The WHO global influenza programme (GIP) provides worldwide surveillance against influenza. GIP collects data and analyzes data on epidemiology and viral strains. WHO has provided this data to the nations to help in the policy making of different nations to prepare against influenza transmission, and identification of high risk group patients and to prevent influenza spread.

Source: news-medical.net

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GLOBAL NEWS

2. Cancer Research UK funds to tackle cancer

Cancer Research UK has pledged to tackle the challenging global cancer with a £60 million fund. This is a part of Cancer research UK's Grand Challenge Project to research on novel pathways for treating cancer and preventing high risk death. The funding has been initiated for the research on microbiome, chronic inflammation, and specific to certain tissues related to cancer.

Scientists from North America, the UK, Europe and Israel together have come together to combat the disease. The research team is composed of the best in respective fields and collaboration of these researchers will establish research ability to understand how to tackle cancer.

The funding is supported by New York based Mark Foundation for cancer research which will provide £10 million to the project.

Source: pharmatimes.com

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GLOBAL NEWS

3. New class of anti-cancer drugs 'E1 inhibitor' discovered

The scientists from the Medical University of South Carolina (MUSC) have discovered a novel binding site for a class of anti-cancer drugs known as E1 inhibitors. The drug discovery is published in December 2018 in "*Nature Communications*" and will promote drug design of more efficient E1 inhibitors.

Researchers have solved the 3D structures of the proteins and discovered a new site SUMO E1 that is located in the centre of the protein which is a new drug binding site for the development of new E1 receptor inhibitors. E1 inhibitors target the Ubiquitin Proteasome Pathway (UPP), which helps maintain healthy proteins within the cell; however, when it malfunctions, diseases such as cancer can occur.

In preclinical studies, E1 inhibitors have shown potential as anti-cancer agents, but there have been obstacles in getting them to the clinic.

Source: news-medical.net

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GLOBAL NEWS

4. Children with ASD likely to face maltreatment

The Child Abuse Hotline has reported that the children with autism spectrum disorder (ASD) were nearly 2.5 times more likely reported to the Child Abuse Hotline by the age of 8 than children without ASD. This is based on a recent study in Middle Tennessee, USA.

Using the data collection and records through the Centers for Disease Control and Prevention's (CDC) Autism and Development Disabilities Monitoring (ADDM) network, 387 of 24,306 children were identified as having ASD. According to the Child Abuse Hotline, >17% children were identified with ASD compared to 7.4% children without ASD; with six times more females suffering from ASD compared with males.

Children with autism may be vulnerable to maltreatment due to several factors, but many instances may not get reported. Lower levels of family social support along with complex cognitive and language impairments combined with challenging behavior may be factors contributing to maltreatment.

Source: news-medical.net

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PHARMA INDIA

1. India signs MoU with UK for initiation of cancer research

India and UK will collaborate in cancer research, a research memorandum of understanding (MoU) was approved by the central government and signed on 14th Nov 2018.

The main aim of both the countries is to improve cancer outcomes. They will initiate research into affordability, prevention and care of cancer bringing together experts from both India and the UK. Experts will be from different fields including clinical trial, new technology, demographic research and physical science.

The 5-year collaborative bilateral research will be initiated by the Department of Biotechnology (DBT), Ministry of Science and Technology of India and Cancer Research UK (CRUK).

DBT and CRUK will both invest £5 million for pilot study and over 5-year, the total research funding will be £10 million.

The health care across the world is not equipped to meet the high burden of cancer care. The India-UK research plans to align the best researchers, scientistits, and health care organizations to collaborate together to develop cancer care options at low costs.

Source: pharmabiz.com

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PHARMA INDIA

2. TN DCA introduces online services for license applications

The Tamil Nadu Drugs Control Administration (TNDCA) will introduce online licensing system for drug manufactures that will provide quick services in making the process of issuing license easier and more transparent.

The licensing process for the pharmaceutical manufacturing industry will be carried out using digital services from April 2019 onwards, which are currently available only for pharmaceutical traders.

The software will be linked to the Central Drugs Control Office (SUGAM). The license will be issued after a joint inspection of central and state government inspectors.

The digital submission of applications will be taken in action within two months post receiving the application online, after the investigation at manufacturing sites.

Source: pharmabiz.com

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PHARMA INDIA

3. Natco Pharma launches Valsartan-Sacubitril in India

Natco Pharma has launched Valsartan-Sacubitril combination tablet under the brand name VALSAC in India. The drug is indicated for certain types of heart failure.

Sacubitril/valsartan contains a neprilysin (NEP) inhibitor- sacubitril and an angiotensin II receptor blocker- valsartan. VALSAC is launched with 2 strengths - 50 mg and 100 mg at an MRP of Rs. 45 and Rs. 55 per tablet, respectively.

Natco Pharma has focused on developing new formulations and manufacturing active pharmaceutical ingredients. The company's revenue mix comprises of 75% formulations and 11% API.

Source: dsij.in

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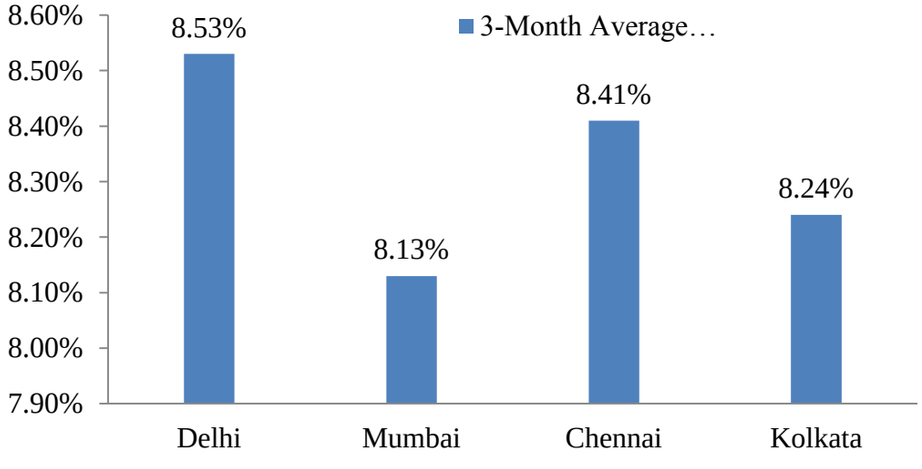
PHARMA INDIA

4. iDCI™ shows high HbA1C in diabetic patients

Novo Nordisk has introduced the India Diabetes Care Index (iDCI™).

iDCI™ has revealed that the three-month average glycated hemoglobin (HbA1c) level of people with diabetes in key cities is high (Delhi: 8.53%, Mumbai: 8.13%, Chennai: 8.41% and Kolkata: 8.24%) against the recommended target of <7%. India on the whole is found to be at an average HbA1c of 8.51%.



HBA1c is the key indicator of long term blood sugar level in diabetic patients and developing diabetic related complications.

In India, 80% of the people have high HBA1c level than recommended levels and 3.14 crore cases of micro- and macro-vascular complications including heart, eye, kidney, nerve and limb disease occur in these patients. The annual diabetes related health care cost was up to Rs. 63,000 crore in 2017.

Source: prnewswire.com

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REGULATORY ROUND-UP

1. FDA issues warning letter on drug-containing balloons, stents

The US Food and Drug Administration (FDA) has issued warning letters to healthcare providers regarding Paclitaxel-coated ballons and Paclitaxel eluting stents.

A meta-analysis from the long-term follow up data have demonstrated increased mortality rate in patients with peripheral arterial disease (PAD) who received treatment with either of the devices.

The patient's mortality rate at two year significantly increased and at five year suddenly decreased after paclitaxel-coated balloons and paclitaxel eluting stents vs. bare device alternatives.

After the publication of this meta-analysis in the Journal "*American Heart Association*", further investigations are urgently warranted.

Source: raps.org

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REGULATORY ROUND-UP

2. FDA's new plan for monitoring dietary supplement

The Food and Drug Administration (FDA) has developed a new plan to significantly modernize regulations and monitoring of dietary supplement. The document will be updated after 25 years.

When the original Dietary Supplement Health and Education Act (DSHEA) was passed, the dietary supplement industry was worth only $4 billion, which is now worth >$40 billion.

More than 50,000 supplement products are available to consumers.

Source: clinicaladvisor.com

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REGULATORY ROUND-UP

3. FDA issues warning to Pharma companies for fake claims

Some pharmaceutical companies are selling tablets, capsules, oils and other food supplement through online and false claiming these can cure Alzheimer's disease. The US Food and Drug Administration (FDA) has issued warning letters to those companies, a few of them from India.

Alzheimer's is serious degenerative disease, has no cure, however, various brain therapies like brain gym, Sudoku and other brain exercises provide benefits to these patients.

Any drug that has not been approved by the drug regulatory authorities could mislead consumers to believe that such therapies can improve the symptoms of the disease, however, this may cause serious or even fatal injuries.

FDA has warned these companies and issued an advisory to the people that unless and until the product is scientifically proven with clinical trials and proven its effects over a period of time, they cannot be relied upon.

Source: pharmabiz.com

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REGULATORY ROUND-UP

4. First untitled letter by OPDP released

The US Food and Drug Administration's (FDA) Office of Prescription Drug Promotion (OPDP) recently released its first untitled letter of 2019.

The letter is released for the promotion of Phoenix Molecular Imaging Center's medical director Fabio Almeida's blog.

As per the untitled letter by OPDP, the blog "suggests in a promotional context" that 11C-Acetate - an investigational drug, is safe and effective. Whereas there is another sentence related to how 11C-Acetate is available under expanded access.

As per FDA, this statement does not convey that the product is investigational. FDA has requested to stop using such statements and listing of all the promotional material for 11C-Acetate.

Source: raps.org

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MERGERS /ACQUISITIONS /COLLABORATIONS

1. Sanofi signs licensing agreement with Biomunex

Sanofi Pharma has collaborated with Biomunex Pharmaceuticals for the development of antibody-based drugs.

Biomunex Pharmaceuticals is focused on immunotherapeutics for different solid tumors (head and neck, gastric, and pancreatic cancer) drug discovery and development.

According to this agreement, Sanofi will get the access to Biomunex's Plug-and-Play BiXAB platform to carry out research for the development of bi- and multi-specific antibody therapeutics.

Bixab therapeutic platform has been used for a variety of cancers, immune-mediated inflammatory diseases and infectious diseases.

Sanofi will make an upfront payment along with clinical, regulatory and commercial milestone payments.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

2. Roche acquires Spark for gene therapy discovery

Roche has signed an agreement with Spark Therapeutics to acquire all shares at $114,50 per share, totaling to around $4.8 billion. Spark Therapeutics' total equity value contains ~$500m net cash that is expected to be paid at the closing of transaction.

Spark Therapeutics is primarily engaged in the discovery, development and delivery of gene therapies for genetic disorders. The disorders include blindness, hemophilia, lysosomal storage disorders and neurodegenerative conditions.

A lead candidate, SPK-8011 is developed for the potential treatment for hemophilia A. The company has also developed SPK-8016 inhibitor for hemophilia A and SPK 9001 for hemophilia B.

Other drug candidates in the pipeline include SPK-7001 for choroideremia, SPK-3006 for Pompe disease and SPK -1001 for CLN2 disease.

The Sparks gene therapy drug Luxturna (voretigene neparvovec-rzyl) has been approved by the US Food and Drug Administration (USFDA) and European Medicines Agency (EMA) for the treatment of biallelic RPE65 mutation associated retinal dystrophy.

Source: pharmaceutical-technology.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

3. Novartis and University of Oxford collaborates for drug development

Novartis and University of Oxford's Big Data Institute (BDI) have announced that they are developing a 5 year research alliance using artificial intelligence (AI) for complex disease drug development. The researchers have planned to analyze huge data sets using AI and machine, to spot disease insights for undetectable diseases so far.

The researchers will combine the data of 5 million patients from the UK and international partner organizations in addition to anonymized data from Novartis clinical trials.

The collaboration will also work towards the identification of unprecedented insights into the characteristics of specific, complex diseases. It will help in understanding what drives disease progression, and understand any commonalities between diseases.

Source: pharmatimes.com

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MERGERS /ACQUISITIONS /COLLABORATIONS

4. Merck, Pfizer combo treatment boosts kidney cancer survival

Merck's cancer immunotherapy drug Keytruda when combined with Pfizer's Inlyta has reduced the risk of death in patients with advanced renal cancer carcinoma (RCC).

Merck said that using this combination, reduction in death rate of 47% was reported in a late stage trial. The combination of drugs also improves the progression free survival and increases the response rate with chemotherapy.

Once this combination treatment is approved by the regulatory agencies to treat patients with RCC, Merck will be again in the competition with Opdivo, which is already being used in combination with Yervoy to treat kidney cancer.

Source: economictimes.indiatimes.com

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DRUGS: APPROVALS AND LAUNCHES

1. EMA orphan drug designation to TLC178

European Medicines Agency (EMA) has approved TLC178 orphan drug for the treatment of soft tissue sarcoma. TLC178 is developed by the Taiwan Liposome Company Ltd. The drug is also approved by the US Food and drug administration (USFDA) for the treatment of rare pediatric disease designation in Rhabdomyosarcoma (RMS).

Soft tissue sarcoma is a rare type of cancer that begins in the body's connective and supportive tissues such as cartilage, fat, muscle, blood vessels.

TLC178 contains vinorelbine as anti-cancer agent and it belongs to vinca alkaloid chemotherapy category. It is formulated by nanox liposomal technology. TLC178 has been designed to increase the tolerability of vinorelbine dose by increasing its therapeutic window.

A Phase I/II, open-label, multicentre, dose escalation trial is currently underway to evaluate the maximum tolerated dose of TLC178 in adult patients with advanced cancers.

Source: healio.com

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DRUGS: APPROVALS AND LAUNCHES

2. Glenmark receives USFDA approval for generic sevelamer

Glenmark Pharma has announced that they have received approval for sevelamer hydrochloride tablet from the US Food and Drug Administration (USFDA).

Sevelamer hydrochloride tablet is indicated to control serum phosphorus levels in patients with chronic renal disease who are on dialysis.

The drug is the generic version and therapeutic biosimilar to Renagel tablets and the product strengths are 400 mg and 800 mg.

Renagel brand and generic had sales of $102.1 million at the end of December 2018.

Source: economictimes.indiatimes.com

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DRUGS: APPROVALS AND LAUNCHES

3. USFDA approves expanded use of Soliqua

The US Food and Drug Administration (FDA) has approved the expanded use of Soliqua 100/33 (insulin glargine and lixisenatide injection) 100 Units/mL and 33 µg/mL.

The drug was initially approved for the use in adults with type 2 diabetes who can't control diabetes on diet and exercise alone and could require some additional drugs to control their blood sugar level. The approval was based on a clinical trial in adult patients with uncontrolled type II diabetes who are on metformin or other oral anti diabetic.

Patients were treated with Soliqua 100/33 and demonstrated potential reduction in blood glucose level compared with insulin glargine (59%) and lixisenatide (33%) alone. The common adverse effects reported were nausea and vomiting in the trial.

Source: pharmabiz.com

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DRUGS: APPROVALS AND LAUNCHES

4. Lupin launches chronic angina treatment drug in US

Lupin has launched semi exclusive generic ranolazine extended release (ER) tablets for the treatment of chronic angina in the US.

The drug is a therapeutic biosimilar and generic version of Gilead Sciences' Ranexa ER and the product strengths are 500 mg and 1,000 mg.

Ranolazine ER had annual sales of approximately $945 million in the US as per IQVIA MAT December 2018 data.

Source: economictimes.indiatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. United Neuroscience gets positive results for Alzheimer's vaccine

United Neuroscience has developed a novel synthetic peptide vaccine that can target the N-terminus of ß-amyloid. The company has got positive results for its UB-311 vaccine from a Phase II clinical trial for Alzheimer's disease.

Currently, there is no potential vaccine available for targeting N- terminus of ß-amyloid. UB-311 is a novel UBITh active vaccine targeting the N-terminus of Aß peptides, the most advanced Alzheimer's vaccine in all clinical development.

The novel synthetic peptide vaccine targeting beta amyloid met the primary aims of safety and immunogenicity with a 96% response rate. The results of secondary endpoints will be presented in next meetings, such as the 14th International Conference on Alzheimer's and Parkinson's Diseases.

Source: pharmatimes.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

2. Xtandi shows positive results in Phase 3 study in metastatic prostate cancer

Pfizer and Astellas Pharma have announced that they have got positive results for Xtandi in the Phase III ARCHES clinical trial for metastatic hormone-sensitive prostate cancer.

The ARCHES Phase III was a randomized, double-blind, placebo controlled and multinational study that enrolled 1,150 patients with metastatic, hormone-sensitive prostate cancer. The patients have received enzalutamide 160 mg daily or placebo with history of orchiectomy.

The results show that Xtandi (enzalutamide) plus androgen deprivation therapy (ADT) met the primary endpoint by significantly reducing the risk of radiographic progression or death by 61% versus ADT alone (n=1,150; HR=0.39 [95% CI: 0.30-0.50]; p<0.0001).

The ARCHES trial demonstrated Enzalutamide with ADT delayed disease progression; it can be significant treatment option for men with metastatic prostate cancer.

Source: pharmabiz.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

3. Abbvie and Teneobio to co-develop TNB-383B for multiple myeloma

TNB-383B is an immunotherapeutic designed to target B-cell maturation antigen (BCMA). BCMA is considered a good target for treating multiple myeloma.

Teneobio's anti-CD3 agent TNB-383B simultaneously targets the BCMA and CD3, which potentially activates the immune system to identify and kill BCMA tumor cells. The T-cell redirection is the novel approach of Teneobios.

Abbvie will have a partnership with Teneobio to develop TNB-383B in Phase I with a planning to initiate a clinical programme for the product in the first half of 2019.

Source: pharmaceutical-technology.com

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

4. New pill can deliver insulin through stomach

A research team at the Massachusetts Institute of Technology has developed a drug capsule that could be used to deliver oral doses of insulin, potentially replacing the injections that people with type 1 diabetes have to give themselves every day.

These capsules contain a small needle made of compressed insulin, which is injected after the capsule reaches the stomach. The drug dissolution rates can be controlled once the tip of the needle is injected into the stomach wall.

In preclinical studies, researchers have shown that enough insulin can be delivered to lower blood sugar to levels comparable to the injections given through skin.

Source: pharmajournalist.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

1. Teva settles dispute with Amgen Pharma

Teva Pharmaceutical has announced that they have solved the current dispute with Amgen over generic cinacalcet HCL product. Teva has recently received the approval and has launched its generic product in the US market.

According to the settlement, Teva has agreed to stop selling its generic product till the license date in mid-2021 or till under certain circumstances and in return Teva will pay an undisclosed amount as part of the settlement to Amgen.

Cinacalcet acts as calcimimetic by allosteric activation of calcium-sensing receptor. Cinacalcet is used to treat secondary hyperparathyroidism (elevated parathyroid hormone levels) in patients with chronic kidney disease, hypercalcemia in people with parathyroid carcinoma.

Cinacalcet can also be used to treat severe hypercalcemia in patients with primary hyperparathyroidism and those patients who are unable to undergo surgery of parathyroid gland.

Source: pharmabiz.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

2. Takeda to pay fine for patent infringement

Jury from the US federal court has ordered Takeda pharmaceuticals to pay $155M to Bayer for patent infringement of a hemophilia drug.

Baxalta, a unit of Takeda was acquired by Shire Biotechnology Company in 2016 and Shire was acquired by Takeda for $59 billion in 2016.

Bayer argued that Baxalta's Adynovate infringed on its patent on recombinant Factor VIII technology for hemophilia.

The jury has agreed on all four claims of Bayer. Both the companies have settled on a reasonable royalty rate of $155M.

Source: fiercepharma.com

PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

3. Perrigo settles patent litigation for efinaconazole topical solution

Perrigo Pharmaceuticals Company has announced that they have settled with Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals Ireland LTD, Dow Pharmaceuticals Sciences, Inc and Kaken Pharmaceuticals Co, LTD related to its Hatch-Waxman litigation for first-to-file Abbreviated New Drug Application (ANDA) for the generic equivalent to Jublia (efinaconazole) 10% topical solution.

The topical product is the most recent example of developing specialized pharmaceutical solutions.

Source: pharmabiz.com

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PATENTS: NEW APPROVALS /LITIGATIONS /SETTLEMENTS

4. Mylan files '514' patent challenge against Biogen's Tecfidera

Mylan
Better Health for a Better World

Biogen will have to face a big hit in the early next year if Mylan gets Tecfidera patent. The US patent and Trademark Office has decided to put a 2028 Tecfidera patent under inter review after an application from Mylan.

Tecfidera is the top most selling drug of Biogen. Tecfidera made $4.27 billion last year as per the annual report disclosed to the patent review board.

The Patent Appeal board will hear arguments for multiple sclerosis drug's 514 patent and will provide its decision the early next year. The 514 patent is vital to the Tecifidera as its other patents expire in this and next year.

Biogen

Biogen believes that they can win the patent dispute with Mylan.

Source: fiercepharma.com

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TECHNOLOGY /NDDS

1. Early diagnosis of lung cancer through graphene biosensor

Researchers at the Exeter University in London have developed a new graphene-based biosensor technology for early diagnosis of lung cancer. This biosensor is very sensitive, selective, and specific. It can detect biomarkers like ethanol, isopropanol and acetone with different concentrations. The device has been described in '*Nanoscale*' journal.

The biosensor can identify specific components of vapor mixture and analyze its chemical make-up to identify causes of cancer. Researchers believe that the device can become a cheap, reusable, and accurate breath test for early stage lung cancer detection.

Lung cancer is the most common and aggressive cancer with ~1.4 million deaths. The main reason of the high mortality due to lung cancer is the lack of clinical symptoms and many of the patients are diagnosed at later stages when the cancer is difficult to treat.

Source: economictimes.indiatimes.com

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TECHNOLOGY /NDDS

2. New smart pill to track ulcers, cancer and other intestinal conditions

New York MIT engineers have developed an ingestible pill to track ulcers, cancers and other intestinal conditions. The ingestible pill upon reaching the stomach quickly swells to the size of a soft, squishy ping-pong ball.

The pill is made up of two types of hydrogel, mixtures of polymer and water. The experiment was done in laboratory with different solutions of water and gastric juices.

Expanded pill is jell-o-like smart pill that when swallowed stays in the stomach and becomes a soft, squishy ping pong ball which can potentially track patients' health. The pill is embedded with sensors that can track stomach temperature up to 30 days, pH levels, signs of certain bacteria and viruses.

The pill can be removed with the help of a calcium solution that causes the pill to shrink to its original size and can be excreted safely out of the body. The study is published in "*Nature Communications*" journal.

Source: economictimes.indiatimes.com

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TECHNOLOGY /NDDS

3. Pacemakers powered by heartbeats

Researchers at the Second Military Medical University and Shanghai Jiao Tong University have developed pacemakers that can be powered by the energy of heartbeats. These pacemakers have been successfully tested in pigs and the study is published in the *"ACS Nano"* journal.

Countless lives could be saved by implantable pacemakers regulating heart rhythm. However, their batteries last only five to 12 years, which is a very challenging issue and at that point they have to be replaced surgically.

Researchers have tried to build pacemakers that use the natural energy of heartbeats as an alternative energy source – which is a step towards making a self-powered cardiac pacemaker.

Source: economictimes.indiatimes.com

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TECHNOLOGY /NDDS

4. New drug delivery technology for renal disease

Aptamers are emerging therapeutic peptide molecules that can bind to a specific target site. They can fold in to secondary and tertiary structures and can be attached to a variety of therapeutic compounds for targeted drug delivery.

AstraZeneca will use Aptamer Group's proprietary technology to explore the potential of developing novel drug delivery devices called Aptamer Drug Conjugates (ApDCs).

AstraZeneca can explore potential new modalities in the early-stage drug development process. AstraZeneca said that renal drug delivery of oligonucleotides was challenging for them but this collaboration makes it easier for renal drug delivery targets.

Source: med-technews.com

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WHAT'S NEW AT LAMBDA

1. Successful completion of AEMPS (Spain) inspection at Mumbai facility

The Spanish Agency of Medicines and Medical Devices 'AEMPS (Agencia Española de Medicamentos y Productos Sanitarios)' completed inspection of the bio-availability/bio-equivalence (BA/BE) clinical facility of Lambda Therapeutic Research Limited at Mumbai in Maharashtra, India, from 04 to 08 February 2019. The audit was successful without any critical observations. The inspection by the AEMPS inspectors has reinforced Lambda's consistent performance and capabilities in conducting BA/BE studies.

2. Successful completion of AEMPS (Spain) inspection at Mehsana facility

The Spanish Agency of Medicines and Medical Devices 'AEMPS (Agencia Española de Medicamentos y Productos Sanitarios)' completed inspection of another BA/BE clinical facility of Lambda Therapeutic Research Limited at Mehsana in Gujarat, India, from 11 to 15 February 2019. The clinical phase of two BA/BE studies were inspected during this audit. The audit was successful without any critical observations. This was the first audit from any EU regulatory Authority at Lambda's Mehsana facility and its successful completion reiterates our constant endeavor and commitment towards quality.

3. Successful completion of AGES (Austria) inspection

The Austrian Agency for Health and Food Safety (AGES) authority initiated its inspection from 30 Jan 2019 to 01 Feb 2019 at one of the clinical trial sites (Surat) for a patient based bioequivalence (BE) study conducted by Lambda. This inspection was extended from 04 Feb 2019 to 06 Feb 2019 for study management oversight of the identified study at Lambda's Ahmedabad facility. The audit was successful without any critical observations.

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